5/4/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

d1749b

Food & Drug Administration
Olympic Towers, Suite 100
300 Pearl Street
Buffalo, NY 14202

April 16, 1998

WARNING LETTER BUF #98-6

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mark S. O'Halla, Executive VP/COO
Clifton Springs Hospital and Clinic
Two Coulter Road
Clifton Springs, New York 14432

Dear Mr. O'Halla:

During an inspection of the Clifton Springs Hospital and Clinic Blood Bank in Clifton Springs, New York, from March 17-19, 1998, Steven J. Libal, an investigator with the Buffalo District Office of the Food and Drug Administration (FDA), documented violations of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680 as follows:

Failure to maintain records concurrently with the performance of each significant step in the collection of each unit of autologous blood [21 CFR 606.160(a)]. Records for four units of autologous blood [redacted] and [redacted] indicated full units by weight were collected when in fact none of these units were collected from the autologous donors.

Failure to always collect autologous blood and maintain records in accordance with standard operating procedures [21 CFR 606.160(b)]. Four of forty-three donor records reviewed lacked a signed donor consent. Blood units are not being drawn at the weight specified in the written procedures. No infectious disease test results were on file for units [redacted] and [redacted] which were shipped to other hospitals.

Failure to assure that all written standard operating procedures related to the collection of autologous blood are consistent regarding donor suitability specifications [21 CFR 160.100(b)]. The Pre-deposit Autologous Blood procedure calls for a donor hematocrit of 33 percent or greater. The Physician Request for Autologous Transfusion and the Donor History Form call for a hematocrit of 34 percent or greater. The Pre-deposit Autologous Blood procedure specifies donor weight of 110 pounds or greater. The Physician Request for Autologous Transfusion specifies donor weight of 100 pounds or greater.

Failure to assure that all autologous blood donation records are complete and all unexplained discrepancies or failures to meet specifications are thoroughly investigated and documented [21 CFR 606.100(c)]. The Donor History Form for patient [redacted] (Units # [redacted] and # [redacted]) lacks answers to questions regarding chest pain and heart/lung disease. The Donor History Form for patient [redacted] shows a hemoglobin result of [redacted] gm/dl. Unit [redacted] was collected without an evaluation of this low result. The Donor History Form for patient [redacted] (Units [redacted] and [redacted]) does not include any responses to the medical history questions.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility as Chief Operating Officer to assure that your establishment is in compliance with all requirements of the federal regulations.

At the conclusion of the inspection, a form FDA-483, Notice of Inspectional Observations, was issued to Dr. Peter Y. Lee, Laboratory Director. A copy is attached for your information. Dr. Lee and his staff promised to initiate corrections during the exit discussion with Investigator Libal. However, you should take prompt measures to assure that the promised corrections have been implemented. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action may include seizure and/or injunction.

Please notify this office in writing, within 15 days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and the time frame within which the corrections will be completed. Your reply should be sent to:

Joseph Erdmann, Team Leader
Food and Drug Administration
P.O. Box 7197
Syracuse, New York 13261-7197.

Sincerely,

Brenda J. Holman
District Director

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Enclosure: FDA-483

cc: Peter Y Lee, MD, Laboratory Director
Clifton Springs Hospital and C'nic
Blood Bank
Two Coulter Road
Clifton Springs, New York 14432